



Direct Healthcare Professional Communication

August 2026

Potential Risk of Nephrolithiasis (Kidney Stones) Secondary to Urinary Retention Symptoms Associated with Sertraline

Dear Healthcare Professional,

Based on recommendations from the Pharmaceutical Vigilance Committee regarding a potential safety signal linking nephrolithiasis (kidney stones) to the administration of sertraline, the Pharmaceutical Vigilance General Administration (PVGA) of the Egyptian Drug Authority (EDA) wishes to inform neurologists, psychiatrists, internal medicine physicians, urologists, and other healthcare professionals of this important safety finding.

Summary

A total of 66 case reports of nephrolithiasis (kidney stones) associated with sertraline use were reviewed. Upon assessment of all available data, including supporting literature, evidence was identified supporting a potential association between sertraline use and nephrolithiasis.

Key findings include:

- Cases were reported from **11 countries**.
- Most patients were **middle-aged adults**.
- Time to onset of nephrolithiasis (kidney stones) after initiation of sertraline ranged from **3 to 6 months**.
- The cases reported in Egypt by physicians recovered following sertraline withdrawal; most of them received a dose of 100–150 mg/day.

Additional:

The biological plausibility of this association is supported by evidence suggesting that serotonergic modulation by SSRIs may increase sympathetic activity while reducing parasympathetic control of voiding. This physiological effect may increase post-void residual urine volume (urinary retention), potentially promoting urinary stasis and increasing the risk of upper urinary tract stone formation, particularly during long-term treatment [1-2].

Recommendations for Healthcare Professionals

- Monitor patients receiving sertraline, particularly during dose escalation (100–150 mg/day) and long-term treatment, for signs and symptoms of nephrolithiasis.
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- Promptly investigate flank pain, abdominal pain, or hematuria; consider urinalysis and renal ultrasonography if nephrolithiasis is suspected.
- Assess patients for risk factors, including relevant comorbidities and concomitant medications associated with an increased risk of kidney stone formation, before initiating sertraline or other SSRIs.

Background

Sertraline is a selective serotonin reuptake inhibitor (SSRI). Serotonin in the central nervous system plays a role in regulating mood, personality, and wakefulness, which is why blocking serotonin reuptake is beneficial in disorders such as major depression, panic disorder, and anxiety disorders [3]. The metabolites are excreted in feces and urine in equal amounts. Only a small amount (<0.2%) of unchanged sertraline is excreted in the urine [4].

Nephrolithiasis (kidney stone = renal stone) is a common condition characterized by the formation of urinary stones, often presenting with hematuria and abdominal, flank, or groin pain. It affects approximately 1 in 11 individuals during their lifetime. Stone formation is related to reduced urine volume or increased excretion of stone-forming substances, including calcium, oxalate, uric acid, cystine, xanthine, and phosphate. Calcium-containing stones account for 60–80% of cases, followed by struvite (10–15%), uric acid (5–10%), cystine (1%), and other rare stone types, including drug-induced calculi [5-6].

References

- 1- <https://pubmed.ncbi.nlm.nih.gov/37513941/>
- 2- <https://pmc.ncbi.nlm.nih.gov/articles/PMC4990176/>
- 3- <https://www.ncbi.nlm.nih.gov/books/NBK547689/>
- 4- <https://www.medicines.org.uk/emc/product/5760/smpc>
- 5- <https://www.ncbi.nlm.nih.gov/books/NBK442014/>
- 6- <https://pubmed.ncbi.nlm.nih.gov/41640900/>

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://vigiflow-eforms.who-umc.org/eg/med>

QR Code:

Hotline: 15301

